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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,331	09/02/2004	Christopher Daly	22409-00050-US1	8801
30678 7590 02/19/2010 CONNOLLY BOVE LODGE & HUTZ LLP 1875 EYE STREET, N.W. SUITE 1100 WASHINGTON, DC 20006				
EXAMINER				
PATTON, AMANDA K				
ART UNIT		PAPER NUMBER		
3762				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,331

Applicant(s)

DALY ET AL.

Examiner

Amanda Patton

Art Unit

3762

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-46, 48, 50-54, 57-65, 67-69, 80, 82-84, 87 and 89-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 87, 89-91, 99 and 100 is/are allowed.
- 6) ☒ Claim(s) 41-46, 48, 50-54, 57-65, 67-69, 80, 82-84 and 92-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-646)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Applicant's amendment dated November 2, 2009, is acknowledged. Currently claims 41-46, 48, 50-54, 57-65, 67-69, 80, 82-84, 87, and 89-100 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41-42, 45-46, 48, 50, 51 and 57-58, 61-65, 92-98, are rejected under 35 U.S.C. 102(b) as being anticipated by Faltys et al. (US Pat. 6,272,382).

Regarding **claim 92**, Faltys disclose the claimed invention including (e.g. ICS of Figures 4A-4C): a housing comprising a receiver coil (e.g. coil 20) and a receiver stimulator package (e.g. ICS circuitry 14 including integrated circuitry 86) substantially aligned along a longitudinal axis (e.g. cutaway axis as shown in Figure 4C by the dotted line) wherein the receiver/stimulator package is configured to output stimulation signals (e.g. cochlear stimulator module; Col. 12, line 35); and a first electrode assembly having contiguous first and second region (e.g. electrode array 12), wherein the first region extends from the housing along a lateral axis substantially perpendicular to the longitudinal axis (e.g. horizontal axis of Figure 4C wherein the electrode array, not shown in Figure 4C, extends as shown in Figure 3A), wherein the lateral axis extends through the housing between a center of the receiver coil and a center of the receiver/stimulator

package (e.g. as shown in Figure 4C), and wherein the first region and the housing are configured such when the second region is disposed in the cochlea, the housing is rotatable about a rotational axis substantially parallel with the lateral axis, and wherein the housing is rotatable such that the second region remains substantially stationary during the rotation (e.g. electrode array 12 is flexible and thus can be held in place while the ICS is rotated around the lateral axis)..

It is also noted that as the claims are apparatus claims, the apparatus need not be shown **actually rotated** into a second position (which would be a method step in an apparatus claim), but only needs to be **capable of being rotated**. Due to the flexible nature of the electrode array 12 the housing of Faltys could be easily moved into a second orientation without substantially moving the cochlear electrode array simply by holding or stapling the electrode array in place and flipping the housing device. The claims as currently filed do not require that the device be operational in the second rotated position (although there is no reason that the device of Faltys would not be operational in a second position).

Regarding **claim 94**, Faltys additionally teaches a device wherein the lateral axis extends between the receiver coil and the receiver/stimulator package (e.g. horizontal axis as shown in Figure 4C).

Regarding **claim 97**, Faltys additionally teaches a device where the lateral axis intersects the longitudinal axis at a position substantially in the middle of the housing (e.g. horizontal axis as shown in Figure 4C).

Regarding **claims 93, 95-96, and 98**, Faltys additionally teaches a housing that is rotatable between a first implant orientation in which the receiver/stimulator package is disposed closed to an outer ear of the recipient than is the receiver coil, and a second implant orientation

in which the receiver coil is disposed closer to the outer ear than the receiver/stimulator package (e.g. housing is capable of being rotated and placed in one orientation such that the coil is closer to the outer ear and one when the receiver is closer to the outer ear, implanting the device as shown in Figure 4A and implanting the device inverted). It is also noted that as the claims are apparatus claims, the apparatus need not be shown **actually implanted** in an implant second orientation (which would be a method step in an apparatus claim), but only needs to be **capable of being implanted** in a first and second implant orientation. Due to the flexible nature of electrode array the housing of Faltys could be easily moved or flipped approximately 180 degrees (e.g. claim 96) into a second orientation without substantially moving the cochlear electrode array simply by holding or stapling the electrode array in place and flipping the housing device. The claims as currently filed do not require that the device be operational in the second implant position (although there is no reason that the device of Faltys would not be operational in a flipped position).

Regarding **claims 41-42, and 57-58**, Faltys additionally teaches two lateral surfaces (e.g. upper and lower circular surfaces of ICS 10) wherein the surfaces are capable of being located closer and farther from the cochlea depending on the implant position, and such that the electrode array is connected to the first lateral surface via the side cylindrical side surface (e.g. as shown in Figure 3B).

Regarding **claims 45-46 and 61-62**, Faltys additionally teaches a housing that is substantially symmetrically about a plane that is parallel and a plane that is perpendicular to the lateral axis (e.g. Figure 4A).

Regarding **claim 48**, Faltys additionally teaches an external component (e.g. external speech processor ESP, Col. 5, lines 30-35), and wherein the receiver coil is configured to receive RF signals from the external component.

Regarding **claim 50**, Faltys additionally teaches a receiver coil further configured to allow transcutaneous bidirectional data transfer between the implantable component and the external component (e.g. as shown through bidirectional arrows in Figure 1A-1E).

Regarding **claim 51 and 63-65**, Faltys additionally teaches that it was known in the art to use an external component in cochlear implant system comprising a microphone configured to receive an inputted sound and convert it into a coupled signal which is converted into stimulation signals (e.g. microphone 104 located in headpiece HP 106; Col. 7, lines 60-66).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-44, 59-60, and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys in view of Berrang et al. (US Pat. 6,648,914, as previously cited).

Regarding **claims 43-44, 59-60, and 80**, Faltys does not expressly disclose a housing comprising at least a portion formed of resiliently flexible material. Berrang, however, discloses that it was known in the art to use a housing that is at least partially formed from resiliently flexible material (e.g. pliable bridge 6). It would have been obvious to one having ordinary skill

in the art at the time the invention was made to include the resiliently flexible material of Berrang in the ICS device of Faltys in order to provide the system with the predictable result of a device capable of being easily implanted into a patient.

Claims 52-54, 67-69, and 82-84, are rejected under 35 U.S.C. 103(a) as being unpatentable over Faltys in view of Carter et al. (US Pat. 6,205360, as previously cited)

Regarding **claims 52, 67, and 82**, Faltys does not teach an implantable component comprising a second electrode assembly. Carter teaches a second extra-cochlear electrode assembly 13 (e.g. Figure 1; Col. 6, lines 10-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a second extra-cochlear electrode array in the device of Faltys in order to provide the predictable results of a reference electrode not affected by stimulation in the cochlea.

Regarding **claims 53-54, 68-69, and 83-84**, Faltys and Carter disclose the claimed invention but does not disclose expressly a second electrode assembly connected to a lateral surface of the housing opposing the first electrode assembly and substantially aligned with a longitudinal axis of the electrode array. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the second electrode array as taught by Faltys and Carter with the specific placement of the second electrode array, because Applicant has not disclosed that the array placement provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the electrode array arrangement as taught by Faltys and Carter, because it provides proper electrode array placement and since it appears to be

an arbitrary design consideration which fails to patentably distinguish over Faltys and Carter. Therefore, it would have been an obvious matter of design choice to modify Faltys and Carter to obtain the invention as specified in the claims.

Allowable Subject Matter

Claims 87, 89-91, and 99-100 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762